IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit:

CHANG ET AL.

Examiner:

APPLICATION NO: TBA (div. of 08/974,391)

Atty. Docket: 4-31401A

FILED: Herewith

FOR: VECTORS FOR TISSUE-SPECIFIC REPLICATION AND GENE

EXPRESSION

Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 MAIL STOP: PATENT APPLICATION

PRELIMINARY AMENDMENT

Sir:

Please cancel claims 1-37 prior to calculating the filing fee in this application.

Remarks

Claims 1-37 in parent application No. 08/974,391, were subject to a restriction/election requirement dated 2/8/99 (copy enclosed) whereby the claims were grouped as follows: Group I – claims 1-19, 25, and 28-29; Group II – claims 20-24 and 26; Group III – claims 30 and 32; Group IV – claims 27, 31, and 33-37. Group I was elected in parent application No. 08/974,391. Claims 38-96 of the instant application correspond to the original Group II claims (20-24 and 26).

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 430 East Hanover, NJ 07936-1080 (301) 258-4715

Date: June 24, 2003

J.Timothy Meigs Attorney for Applicants

Reg. No. 38,241



UNITED STAT DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 roun Art Cast

			विकास हैते. विकास		132	
APPLICATION NO			MED INVENTOR	AT	TORNEY DOCKET NO	体的
08/974.3	391 11/19	/97 CHANG	***			
Tids auton-s Fifting	•	HM12	/0208 _	EX	(AMINER	
os somerney	KESSLER* G JYORK AVEN	OLDSTEIN & MED WE, MEW WAR ACT	X formal marters, 2 1. D. 11. 453 C	บานานานุบน 191-6	and house in the pass	¥
A shorter SUITE 60	00 CON DC 2000	5.52934 st. fa.65	remise's <u>i</u> to resorted with a	mrART,UNITS Street of the period of the seriod of the seri	กษายร วับปุลสบรณชา	; £
spriidthion to become e 14 1344 (1 1386-4)	erate of the second second	Special (1986) Extens	enrat ine den	be spyshloc imde. : DATE MAILED:	the 27062708799	Э
happis like to elleline						
Y Claudes 127		and the second s	and the state of t	_ means pearing	In the application.	
Of the above, or	Marine St.	en de la companya de	ه رو بيو والمناصريات والإمام ال	iskaid villa.di aen	· 在 4 / 1 / 李素型的基础的	<u> </u>
Please find below	w and/or attacl	hed an Office comm	nunication con	cerning this app	olication or	1.
Clarofa Estanca / 37				is/are (in) Commissioner of P to regardation or e	atents and Tradema	arks
Apficación Proces						
Ti See the tip of the		erinto s Pace m Deese	ra. PTO: 2			
The crive DO	CKETE		r in the East	rings.	•	
		Last in		in the second of the second		

Restriction/Election March 10, 1999 Ltat Bar August 19, 1999

というなお 変な (Min gri 4) とここと

ng khara na Nibolak i ka<mark>ro</mark>

GIT RANGE AND CONTRACT OF A STORY SIZE

Filhering of the property of the control of the con

There is an isolate to live the an employees

Disposition of the contract of the contract of

simeral riduid Gerara Coope (la mosco)

RWE or reason is com number ancho application from the entire of Burgarian Billion

PTO-900 (Rev. 2/95)

1, 14,0,71,744 1.1

Office Action Summary

Application No.

Applicant(s)

08/974,391

Chang et al.

Examiner

Karen M. Hauda

Group Art Unit 1632



Responsive to communication(s) filed on	•
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D.	· ·
A shortened statutory period for response to this action is set to expir is longer, from the mailing date of this communication. Failure to respapplication to become abandoned. (35 U.S.C. § 133). Extensions of 37 CFR 1.136(a).	oond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed
Claim(s)	is/are rejected.
Claim(s)	is/are objected to.
	are subject to restriction or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent Drawing Review The drawing(s) filed on	by the Examiner. isapproveddisapproved. 35 U.S.C. § 119(a)-(d). priority documents have been ational Bureau (PCT Rule 17.2(a)).
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FO	LLUVVIIVG PAGES

Application/Control Number: 08/974,391

Art Unit: 1632

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, 25 and 28-29, drawn to a vector comprising a first and second coding sequence, host cells containing the same, and methods of making the same, classified in class 435, subclass 320.1.
- II. Claims 20-24 and 26, drawn to a virion, host cells containing the same, and methods of producing the same, classified in class 435, subclass 456.
- III. Claims 30 and 32, drawn to a method of modulating the replication of a vector, classified in class 435, subclass 375.
- IV. Claims 27, 31 and 33-37, drawn to a method for introducing a vector into a cell in vitro or in vivo, and methods of diagnosing cell replication and treating a tumor in a patient, classified in class 514 or 435, subclass 44 or 69.1, respectively.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Groups III and IV are materially different methods for using the product of Group I,

Art Unit: 1632

such that the product as claimed can be used in a materially different process. Additionally, the vector of Group I can be used as a hybridization probe, for example. The distinction between inventions I and III-IV is further underscored by their divergent subject matter and independent search status.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and II have different modes of operation, are produced by different reagents and methodologies, and can be used in materially different methods. For example, virions can be used to make producer cells. The distinction between inventions I and II is further underscored by their divergent subject matter and independent search status.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are materially different processes which are not used together. The method of expressing a gene in vitro or in vivo utilizes different strategies, different reagents, and different technical considerations from a method of modulating the replication of a vector. The distinction between inventions III and IV is further underscored by their divergent subject matter and independent search status.

Application/Control Number: 08/974,391 Page 4

Art Unit: 1632

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen M. Hauda whose telephone number is (703) 305-6608.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian R. Stanton, may be reached at (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2801.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Application/Control Number: 08/974,391

Page 5

Art Unit: 1632

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is or (703) 305-3014 or (703) 308-4242.

Karen M. Handa

" KAREN HAUDA PATENT EXAMINER